AVEO Pharmaceuticals Initiates Patient Enrollment in Phase 1b Tivozanib Combination Trial in Advanced Solid Tumors

November 16, 2010 6:31 AM ET

**Trial to Evaluate Tivozanib in Combination with Widely-Used Oral Xeloda® in Patients with Advanced Breast and Colorectal Cancers**

CAMBRIDGE, Mass., Nov 16, 2010 (BUSINESS WIRE) -- AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today announced that it has initiated patient enrollment in an open-label, multi-center Phase 1b clinical trial evaluating tivozanib in combination with oral capecitabine (Xeloda(R)) in patients with certain advanced solid tumors. This is one of several combination trials ongoing to explore the potential use of tivozanib in combination with leading targeted therapies and chemotherapeutic regimens in multiple cancers including kidney, colorectal and breast cancers.

"Finding a potent and selective oral VEGF inhibitor that safely and effectively combines with other anti-cancer agents would represent a step forward for treating advanced cancers in a variety of tumor types," stated Skip Burris, M.D., chief medical officer and director of drug development at the Sarah Cannon Research Institute. "Combining investigational tivozanib, which targets VEGF receptors 1, 2 and 3 and has demonstrated the potential for favorable safety and tolerability, with an oral chemotherapeutic drug like capecitabine, may offer a therapeutic advance and a convenient dosing regimen for patients with breast and colorectal cancers."

This trial is designed to assess the safety, tolerability and maximum tolerated dose (MTD) of tivozanib when given in combination with oral capecitabine, a chemotherapeutic agent used in the treatment of metastatic breast and colorectal cancers, in approximately 24 patients with advanced solid tumors at three U.S. sites. In the expansion cohort of the trial, up to 12 patients with locally advanced or metastatic breast or colorectal cancer are expected to be enrolled to further evaluate safety and activity of this combination in these tumor types.

"We believe this Phase 1b trial evaluating tivozanib in combination with oral capecitabine in patients with colorectal and breast cancers may provide further evidence of tivozanib's utility as a valuable addition to widely used cancer treatment regimens, in addition to being an effective and tolerable monotherapy option," said Tuan Ha-Ngoc, president and chief executive officer of AVEO. "The clinical data we are generating with tivozanib in our Phase 1b combination studies are informing our development strategy as we look toward potential registration paths in multiple tumor types in the future. We look forward to presenting additional combination data at upcoming medical congresses this year."

**About Tivozanib**

Tivozanib, an investigational new drug, is a highly potent and selective inhibitor of VEGF receptors 1, 2 and 3, exhibiting picomolar inhibitory activity against all three receptors. Due to its potency and specificity, AVEO believes tivozanib may enable optimal inhibition of the VEGF pathway, while minimizing side effects associated with off-target activity. Such a profile may enable tivozanib to be more readily combined with standard chemotherapy as well as other targeted therapies, potentially increasing the breadth of its clinical utility. The EMA has granted AVEO orphan medicinal product designation for tivozanib for the treatment of RCC.

AVEO recently completed patient enrollment ahead of schedule in TIVO-1, a global, randomized (1:1), controlled Phase 3 clinical trial evaluating tivozanib compared to sorafenib (Nexavar(R)) in patients with RCC. The company has initiated a series of clinical trials evaluating tivozanib in combination with other agents in multiple solid tumor settings, including an ongoing Phase 1b trial in combination with temsirolimus (Torisel(R)), an approved mTOR inhibitor, in patients with metastatic renal cell carcinoma; a Phase 1b trial in combination with the FOLFOX6 chemotherapy regimen in patients with advanced colorectal cancer and other gastrointestinal cancers; and a Phase 1b trial in combination with paclitaxel (Taxol(R)) in patients with metastatic breast cancer. A Phase 1b trial evaluating tivozanib as monotherapy in patients with non-small cell lung cancer is also being conducted.

AVEO is also utilizing its Human Response Platform(TM) in its efforts to help identify rational drug combinations and patient populations most likely to be responsive to these combination therapies.
About AVEO

AVEO Pharmaceuticals (NASDAQ: AVEO) integrates a proprietary cancer biology platform with drug development and commercial expertise in its efforts to discover and develop targeted cancer therapeutics. The company's lead product, tivozanib, is an oral, triple VEGF receptor inhibitor with a highly differentiated profile. Tivozanib is currently being investigated in a global, randomized Phase 3 clinical trial called TIVO-1 comparing tivozanib to sorafenib in advanced kidney cancer, as well as additional clinical studies in other solid tumor types. AVEO's second most advanced product candidate, AV-299, is a potent, functional anti-HGF antibody that is currently in Phase 2 development. AVEO's proprietary, integrated cancer biology platform offers the company a unique advantage in oncology drug development and has provided a discovery engine for high-value targets. This approach has resulted in a promising pipeline of monoclonal antibodies against novel targets including HGF, ErbB3, RON, Notch and FGFR. For more information, please visit the company's website at www.aveopharma.com.

Any statements in this press release about our future expectations, plans and prospects, including statements about an oral VEGF inhibitor representing a step forward for treating advanced cancers, the combination of tivozanib with other targeted or chemotherapeutic therapies in multiple cancers, including such combination offering a therapeutic advance and convenient dosing regimen; tivozanib's potential to have a favorable tolerability and safety profile; tivozanib's utility as a valuable addition to widely used cancer treatment regimens and an effective and tolerable monotherapy option; the potential for tivozanib to have broad applicability and combinability with other therapeutic agents; tivozanib possibly enabling optimal inhibition of the VEGF pathway, while minimizing side effects; our cancer biology platform offering a unique advantage in oncology drug development; and other statements containing the words "believes," "anticipates," "plans," "expects," "will" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: our ability to successfully research, develop and obtain and maintain regulatory approvals for tivozanib and our other product candidates; the possibility that favorable data from our Phase 2 clinical trials of tivozanib may not be predictive of the results in TIVO-1 and our other clinical trials; delays in data availability, or negative results from TIVO-1 or our other clinical trials; our inability to obtain and maintain adequate protection for intellectual property rights relating to our product candidates and technologies; unplanned operating expenses; our inability to raise substantial additional funds to achieve our goals, including with respect to the further development of tivozanib; competition; general economic and industry conditions; and other factors discussed in the "Risk Factors" section of our most recent Form 10-Q filed with the Securities and Exchange Commission, and in other filings that we periodically make with the SEC. In addition, the forward-looking statements included in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

SOURCE: AVEO Pharmaceuticals, Inc.

AVEO Pharmaceuticals, Inc.

Investor Contact:
Monique Allaire, 617-299-5810

or

Media Contact:
Pure Communications
Caton Lovett, 910-232-7166